**Section II (Remarks)**

By the present amendment, Claims 1-10 and 12-14 are pending and rejected, and Claims 16-26 have been added. The limitations of Claim 15 have been incorporated into Claim 8, as suggested by the Examiner on page 4 of the June 9, 2009 Office Action.

The Advisory Action mailed on August 14, 2009 did not indicate that the Amendment filed on August 7, 2009 was not entered, so the instant Amendment is being submitted on Applicants' belief that the August 7, 2009 Amendment was entered. The August 7, 2009 Amendment had amended Claims 1, 7 and 12, cancelled Claim 11, and added new claims 13-15. The instant Amendment adds new Claims 16-26.

Claims 16 and 17 are directed to the process of Claim 1, wherein the VA-2914 is in the form of a white crystalline solid (Claim 16), and has a melting point of around 189°C (Claim 17). Support for Claim 16 is found in the specification at least on page 2, lines 1-4, and support for Claim 17 is found in the specification at least on page 7, lines 24-30.

Claim 18 is directed to VA-2914 isopropanol hemisolvate prepared by a process that involves dissolving VA-2914 in isopropanol at a temperature between 75°C and the solvent reflux temperature, allowing the resulting solution to cool down to a temperature between 0°C and 30°C, and isolating the resulting VA-2914 isopropanol hemisolvate crystalline form. Support for Claim 18 is found in the specification at least on page 9, lines 22-30.

Claim 19 depends from Claim 18, and includes the additional step of converting the VA-2914 isopropanol hemisolvate to VA-2914 via recrystallization of the VA-2914 isopropanol hemisolvate in a solvent other than isopropanol. Support for Claim 19 can be found in the specification on page 2, lines 5-8.

Claim 20 depends from Claim 19, and specifies that the recrystallization solvent is ethyl ether or a mixture of ethanol and water. Support for Claim 20 can be found in the specification on page 3, lines 1-5.

Claim 21 depends from Claim 19, and specifies that the VA-2914 is obtained in the form of white crystals. Support for Claim 21 can be found in the specification on page 2, lines 1-4.

Claim 22 depends from Claim 19, and specifies that the VA-2914 has a melting point of around 189°C. Support for Claim 22 can be found in the specification on page 7, lines 24-30.

Claim 23 is directed to isolated VA-2914 isopropanol hemisolvate in crystalline form. As such, it distinguishes over VA-2914 produced by dissolving VA-2914 in isopropanol, removing the solvent by distillation without crystallizing the product, then adding a second solvent to dissolve the material, without a discrete step of isolating the crystalling product. Support for this step is found in the specification on page 2, lines 8-15, which state:

> In another aspect, the invention relates to said VA-2914 isopropanol hemisolvate, which has been identified and characterised by its infrared (IR) spectrum, its exotherm by differential scanning calorimetry (DSC) and its X-ray diffractogram (XRD). The isopropanol content (about 5.9%) in said VA-2914 isopropanol hemisolvate was determined by gas chromatography and analysed by means of the internal standard technique.

That is, it would have been impossible for the VA-2914 isopropanol hemisolvate to have been characterized by IR, DSC, and XRD without it first having been isolated.

Claim 24 is directed to isolated VA-2914, in the form of white crystals. Support for Claim 24 is essentially the same as that of Claim 23, with support for the white color of the crystals found in the specification on page 2, lines 1-4.

Claim 25 is directed to isolated VA-2914, in the form of crystals with a melting point of around 189°C. Support for Claim 23 is essentially the same as that of Claim 23, with support for the melting of the crystals found in the specification on page 7, lines 24-30.

Claim 26 is directed to isolated VA-2914, in the form of white crystals with a melting point of around 189°C. Accordingly, Claim 24 essentially incorporates the limitations of Claims 22 and 23 into a single claim, and support for Claim 26 is essentially the same as the support for Claims 24 and 25.

Accordingly, the newly added claims do not add new matter, as they are fully supported by the specification.

**Telephonic Interview with the Examiner**

Applicants wish to thank the Examiner for the helpful interview held on September 9, 2009. During the interview, the Kim reference was discussed, in connection with earlier-presented claims, and in connection with the newly presented claims. Applicants discussed the fact that Kim did not disclose forming a crystalline isopropanol hemisolvate product and separating the product from an isopropanol mother liquor, and, accordingly, did not disclose removing isopropanol-soluble impurities from any product that was obtained. The purity of the resulting product (VA-2914), and the isolation of a pure intermediate (the VA-2914 isopropanol hemisolvate) was argued to be a distinguishing feature. The Examiner suggested that if Claim 8 was amended as discussed during the interview, she may consider withdrawing the rejection over Kim, but would not necessarily issue a notice of allowance, but rather, she may also conduct a further prior art search.

Applicants also discussed new claims directed to a product prepared according to a particular process, namely, VA-2914 isopropanol hemisolvate prepared by a process that involves dissolving VA-2914 in isopropanol at a temperature between 75°C and the solvent reflux temperature, allowing the resulting solution to cool down to a temperature between 0°C and 30°C, and isolating the resulting VA-2914 isopropanol hemisolvate crystalline form. Also claimed is VA-2914 prepared by recrystallization of the isopropanol hemisolvate in a solvent other than isopropanol (Claims 17-20).

As discussed with the Examiner, there is a difference between recrystallization and a dissolution-evaporation process. For example, in a dissolution-evaporation process using isopropyl alcohol as a solvent, any impurities that are not removed as the solvent is distilled off would remain in the residue when the isopropyl alcohol is removed. In contrast, impurities that are soluble in isopropyl alcohol (or at least a significant portion of such impurities) would remain in the solvent if a material is recrystallized in isopropyl alcohol. As discussed in the specification, and as claimed in the newly added claims, the VA-2914 product produced by first forming and isolating the isopropanol hemisolvate, then recrystallizing this material in another solvent system, is a white crystalline solid with a melting point that is significantly higher than the literature melting point. Given that the material identified in the prior art was a yellow substance with a melting point

several degrees lower, it is clear that the products are not the same. Thus, it is appropriate to claim the product by the process in which it is made.

Also discussed with the Examiner were the claims to an isolated VA-2914 isopropanol hemisolvate in crystalline form, with additional claims specifying that the crystals are white in color and have a melting point of around 189°C. The cited reference failed to disclose isolating VA-2914 isopropanol hemisolvate as a crystalline material, as it failed to disclose a recrystallization step from isopropyl alcohol. Thus, claims to a highly-purified isolated material, and to a highly-purified material prepared by a recrystallization process, are patentable over the disclosure of a less pure, non-crystalline residue resulting from a dissolution-evaporation process.

**Rejection of Claims 1, 5, 8, 9 and 11 Under 35 USC 102(b) Over Kim et al.**

In the June 9, 2009 Office Action, claims 1, 5, 8, 9 and 13 were rejected under 35 USC 102(b) over Kim et al. WO96/30390 ("Kim"). This rejection is respectfully traversed.

Claim 1 of the present application recites:

> *"1. A process for purifying 17a-acetoxy-llfJ-(4-N,N-dimethylaminophenyl)-19norpregna-4,9-diene-3,20-dione (VA-2914) comprising recrystallising raw (VA2914) in isopropanol and forming (VA-2914) isopropanol hemisolvate."*

Recrystallization is a typical procedure in chemistry for purifying compounds. It allows one to separate compounds with different solubility properties in a given solvent or mixture of solvents. By controlling the conditions, the solubility difference can be used to recrystallize a substance. Recrystallization is based on the fact that every molecule has a specific saturation point in each solvent. Therefore, a saturated solution can be prepared and, if the saturation point is overcome (by cooling down, evaporating the solvent, changing the polarity of the solution, etc), the solvent will be unable to contain the solute, and the solute will therefore precipitate as a solid. Under suitable conditions, the solute

might precipitate to form an ordered arrangement, thus forming a crystal lattice. The recrystallized solid is then filtered away from the liquid (mother liquor). All the impurities which are more soluble will remain in the mother liquor after the desired compound has recrystallized and therefore further filtration will allow to purify the compound from said impurities.

There are different recrystallization techniques. However, they all include the following common steps:

1. Dissolving the solute.
2. Crystallizing the solute.
3. Separating the resulting crystals.

In the present application, recrystallization of raw VA-2914 from isopropanol gives rise to the formation of VA-2914 isopropanol hemisolvate crystals. All the steps followed to perform the recrystallization are detailed on page 5 of the originally filed application, including, of course, the three basic steps mentioned above.

Example 2 of the INSTANT application refers to a specific embodiment wherein the solute is dissolved in isopropanol at high temperature, crystals were formed by cooling down the solution and, finally, crystals were collected by filtration. In contrast, according to example 7, page 23, the process followed by Kim et al. is as follows:

> *"The above syrup was dissolved in 300 mL of isopropyl alcohol and evaporated. The dissolution and evaporation was repeated three times. Finally, the remaining solid, which retained isopropyl alcohol as solvent of recrystallization, was dissolved in ethyl acetate and evaporated to give a stable foam. The foam was quickly dissolved in ether, and this solution was set aside to crystallize. The solid that formed was collected by filtration, wash with ether[sic], and dried .... "*

That is, the process disclosed by Kim et al. only comprises the steps of dissolving the raw material in isopropanol, followed by evaporation. Therefore, it does not include the essential steps of a recrystallization procedure and, therefore, it is not a

recrystallization, but a dissolution-evaporation process. As a consequence, it does not allow one to purify the compound from impurities with different solubility, since no separation of the resulting solid from impurities with different solubility is performed.

This type of dissolution-evaporation process are usually employed to remove low boiling point impurities or rest of solvents previously employed. This way, addition of a solvent with a higher boiling point (as isopropanol) will help to drag volatile impurities during its evaporation. Indeed, it can be considered as a distillation process, but never as a recrystallization process. Only low boiling point contaminants will be separated. However, solid impurities, and even any impurities with a boiling point higher than isopropanol, will necessarily be part of the remaining solid.

The fact that Kim et al. state that *"the remaining solid, which retained isopropyl alcohol as solvent of recrystallization, ...* " is irrelevant, since no recrystalization has been carried out. The remaining solid may contain retained isopropanol within the remaining residue. The skilled person reading Kim et al. would never have recrystallized the raw material in isopropanol, but rather, would simply have dissolved and evaporated the resulting solution as.disclosed in Example 7.

In addition, on page 15, lines 19-23, *Kim* et al. disclose that:

> *"the compound of formula I can be purified by crystallization from ether in high yield and high purity (m.p.: 183-185°C)".*

Kim does not disclose or suggest using isopropanol as a recrystallization solvent. In this sense, and as mentioned above, the procedure is described by Kim et al. as follows:

> *"The above syrup was dissolved in 300 mL of isopropyl alcohol and evaporated. The dissolution and evaporation was repeated three times. Finally, the remaining solid, which retained isopropyl alcohol as solvent of recrystallization, was dissolved in ethyl acetate and evaporated to give a stable foam. The foam was quickly dissolved in ether, and this solution was set aside to crystallize. The solid that formed was collected by filtration, wash[ed] with ether, and dried ....* "

That is, the recrystallization from ether is clearly disclosed through the description of the essential steps of a recrystallization process described above. It is therefore clear that the process disclosed by Kim et al. consists of a dissolution-evaporation stage (distillation) in isopropanol, a dissolution-evaporation stage in ethyl acetate and a recrystallization stage from ether. However, said process does not comprise a recrystallization stage from isopropanol. Consequently, the process of Kim et al. does not encompass the process of current claim 1, which is therefore new over Kim et al.

Accordingly, the rejection of claim 1 should be withdrawn.

Claims 5 and 8 include the recrystallization stage from isopropanol and, therefore, are also new. Accordingly, the novelty rejection of claims 5 and 8 should be withdrawn.

Claim 9, defining VA-2914 isopropanol hemisolvate, complies with the novelty requirement as well. As stated above, the process of Kim et al. does not disclose VA-2914 isopropanol hemisolvate, but rather, a residue after distilling the raw material. Indeed, Kim does not even mention forming crystals. Accordingly, the novelty rejection of claim 9 should be withdrawn.

Instant claim 13 refers to a method of producing VA-2914 that comprises providing its isopropanol hemisolvate. Once again, Kim et al. do not disclose VA-2914 isopropanol hemisolvate. Therefore, the claimed method of producing VA-2914 using the isopropanol hemisolvate is necessarily new over Kim et al. Accordingly, the novelty rejection of claim 13 should be withdrawn.

Finally, the Examiner considered (page 3, fourth paragraph of the Office Action) that, according to Example 2 of the instant application, the isopropanol hemisolvate obtained is a cake and not crystals. Applicants respectfully disagree.

A "cake" (or "filter cake") is a common term used to refer to the solid that is retained in the funnel during filtration process, in opposition to the filtrate, which refers to the solution coming through the filter.

The term "cake" is generally used independently of the nature of the solid particles forming it. As mentioned along the whole application, the process of the invention provides VA-2914 isopropanol hemisolvate crystals. Therefore, it is obvious that the cake referred to in Example 2 of the application is a cake formed by hemisolvate crystals. Even more, as mentioned on said example (lines 23-24) the hemisolvate

obtained was characterized by X-ray diffraction, a technique that can only be used to study crystalline structures.

For at least these reasons, Applicants respectfully request that the Examiner withdraw the rejections of claims 1, 5, 8, 9, and 13 under 35 U.S.C. 102 (b).

Application of the Pending Novelty Rejection to Newly Added Claims 16-26

Claims 16-26 are patentable over the cited Kim reference.

Claims 16 and 17 are directed to the process of Claim 1, wherein the VA-2914 is in the form of a white crystalline solid (Claim 16), and has a melting point of around 189°C (Claim 17). The white color of the crystals, as well as the fact that the crystals have a higher melting point than that reported in Kim, are indicative of higher purity. Accordingly, Kim does not disclose the subject matter of Claims 16 or 17

Claim 18 is directed to VA-2914 isopropanol hemisolvate prepared by a process that involves dissolving VA-2914 in isopropanol at a temperature between 75°C and the solvent reflux temperature, allowing the resulting solution to cool down to a temperature between 0°C and 30°C, and isolating the resulting VA-2914 isopropanol hemisolvate crystalline form. Kim never isolated VA-2914 isopropanol hemisolvate from a solution of isopropyl alcohol, but rather, formed an isopropyl alcohol solution of VA-2914, and removed the isopropanol solvent by distillation to obtain a residue, which residue was dissolved in ethyl acetate without an intermediate isolation step. Accordingly, Claim 18 is novel over Kim.

Claim 19 depends from Claim 18, and includes the additional step of converting the VA-2914 isopropanol hemisolvate to VA-2914 via recrystallization of the VA-2914 isopropanol hemisolvate in a solvent other than isopropanol. Since Kim never isolated the VA-2914 isopropanol hemisolvate, Kim further could not have performed an additional step of recrystallizing the VA-2914 isopropanol hemisolvate from a solvent other than isopropanol.

Claim 20 depends from Claim 19, and specifies that the recrystallization solvent is ethyl ether or a mixture of ethanol and water. Kim never used these solvents as recrystallization solvents.

Claim 21 depends from Claim 19, and specifies that the VA-2914 is obtained in the form of white crystals. Kim discloses yellow crystals, not white crystals, and therefore does not disclose the subject matter of Claim 21.

Claim 22 depends from Claim 19, and specifies that the VA-2914 has a melting point of around 189°C. The melting point of the crystals disclosed by Kim is significantly lower.

Claim 23 is directed to isolated VA-2914 isopropanol hemisolvate in crystalline form. As such, it distinguishes over VA-2914 produced by dissolving VA-2914 in isopropanol, removing the solvent by distillation without crystallizing the product, then adding a second solvent to dissolve the material, without a discrete step of isolating the crystalling product.

Claim 24 is directed to isolated VA-2914, in the form of white crystals. As discussed above, Kim only disclosed isolating VA-2914 in the form of yellow crystals, not white crystals.

Claim 25 is directed to isolated VA-2914, in the form of crystals with a melting point of around 189°C. As discussed above, Kim only disclosed isolating VA-2914 in the form of crystals with a lower melting point.

Claim 26 is directed to isolated VA-2914, in the form of white crystals with a melting point of around 189°C. The white color and relatively high melting point are indicative of a VA-2914 product of higher purity than the VA-2914 product disclosed by Kim.

Accordingly, each of these claims are novel over Kim.

**Rejections under 35 USC 103(a)**

The rejection of claims 2-4, 6, 7, 10 and 12 under 35 U.S.C. 103 (a) over Kim, as applied to Claims 1, 5, 8 and 9, above, and, further in view of Cook et al. (WO 99/45022), was maintained from the previous Office Action. The rejection of claims 14 and 15 under 35 U.S.C. 103 (a) over Kim et al., as applied to Claims 1, 5, 8 and 9, above, and, further in view of Cook et al. (WO 99/45022), was also maintained from the previous Office Action. Applicants respectfully traverse these rejections.

As discussed above, the process disclosed by Kim is different from that of the claimed invention. Kim teaches purifying raw VA-2914 by a dissolution-evaporation

stage in isopropanol, followed by a dissolution-evaporation stage in ethyl acetate and a final recrystallization stage from ether. In contrast, the present invention refers to purification of raw VA-2914 through recrystallization from isopropanol followed by recrystallization from ether or ethanol/water. Therefore, the process of the present invention differs from that of Kim in the use of an intermediate recrystallization step from isopropanol, thus providing VA-2914 isopropanol hemisolvate.

Applicants have surprisingly found that the isopropanol hemisolvate presents some specific solubility properties (lower solubility) that allow a better separation from the impurities through recrystallization. As a consequence, the whole process affords VA-2914 with an improved purity. The question then, is to determine whether this step would have been obvious for the skilled artisan in view of the prior art.

As previously mentioned, Kim does not teach or even suggest the possibility of performing a previous recrystallization from isopropanol. It would have never been obvious for the skilled person, in searching for a new method to purify VA-2914, to include a previous step of recrystallizing the raw material from isopropanol. In addition, the process of the invention is not just a mere alternative to purifying VA-2914, but an inventive one. As stated in the application, the process of the invention provides an improved purity. Such improvement was demonstrated by the color and the melting point of the final product.

The Examiner considers that the difference observed between the melting points (189°C vs. 183-185°C) is not significant. We strongly disagree. Melting point is one of the oldest test methods to ascertain purity of organic compounds. The melting point determination is an easy, fast and cost-effective technique still used for gauging purity of organic and pharmaceutical compounds. It is well-known that the melting point of a pure substance is always higher than the melting point of an impure sample of that particular substance.

Mixtures of substances also show a melting range instead of a sharp melting point, as pure substances. The greater the amount of impurity present, the lower the melting point and the wider the melting range. A pure substance melts at a precisely defined temperature, characteristic of every crystalline substance. Therefore, a difference of 4-6°C in the melting point is quite significant.

Moreover, Kim published a paper *(Steroids 2000, 65, 395-400),* copy enclosed, where the results of their previous patent were described (see page 396, first paragraph, last sentence - reference [9] refers to the US patent application whose priority is claimed by Kim). In this paper, the synthesis and purification of VA-2914 (compound 8 of the publication) is described in point 2.7. In this case, the intermediate dissolution-evaporation stage of the raw material in isopropanol was replaced by a dissolution-evaporation stage in ethyl acetate. However, a product with a similar melting point as in their previous patent was obtained, thus indicating that the dissolution-evaporation step in isopropanol did not influence the purity of the final compound. This is in stark contrast to the instantly claimed process, in which the recrystallization step from isopropanol allows one to improve the purity of the product.

In addition, the paper indicates that the final product with a melting point of 183-185°C corresponds to a compound that is only greater than 98% pure. In contrast, the purification process of the invention allows one to prepare material with purity greater than 99.5%, in accordance with the higher melting point observed. A chromatograph showing that the purity degree of said compound (VA2914) is 99.72% is also enclosed.

The Examiner requested comparative experiments wherein the only difference is the method via which the hemisolvate is obtained. However, we submit that the application the process carried out in the application is similar to the one by Kim et al., except from the step where the raw material is treated with isopropanol. The results obtained with the process of the application are shown in Figure 5, which can be compared with product obtained by Kim et al. which purity, as discussed above, is significantly lower. In view of the above, we submit that all the claims of the application are inventive over Kim et al. In addition, the presence of an unexpected result (improved purity) has been demonstrated.

Cook et al. refer to compounds structurally related to VA-2914. However, Cook does not teach using recrystallization to purify the compounds. Therefore, the skilled person in view of this document, either alone or combined with Kim et al., would have never arrived at the process of the invention.

Further, the combination of references does not teach each element of the claims, since neither Cook nor Kim disclose recrystallizing the product from isopropanol. A

combination of references cannot render a claimed process obvious if the combination does not teach each element of the claims.

Claim 12, directed to the carbinol acetate, also fulfills the requirements of novelty and non-obviousness, as acknowledged during the International phase of the corresponding PCT application. Neither Kim nor Cook discloses the specific combination of substituents required to arrive at the compound of claim 12. Accordingly, this compound is novel and non-obvious. In addition, this compound has been found to be useful in the preparation of VA-2914 with an improved purity. Consequently, this compound is a novel and non-obvious intermediate, which can be used in an overall novel and non-obvious process.

For at least these reasons, Applicants respectfully request that the Examiner withdraw the rejections of Claims 1-10 and 12-15 under 35 U.S.C. 103 (a).

Application of the Pending Novelty Rejection to Newly Added Claims 16-26

As discussed below in more detail, Claims 16-26 are patentably non-obvious over the cited Kim reference.

Claims 16 and 17 are directed to the process of Claim 1, wherein the VA-2914 is in the form of a white crystalline solid (Claim 16), and has a melting point of around 189°C (Claim 17). The white color of the crystals, as well as the fact that the crystals have a higher melting point than that reported in Kim, are indicative of higher purity. The melting point and the color of the crystals are also important patentable distinctions in Claims 21, 22, and 24-26. The purity obtained using the process described in the above-reference does not appear to be obtainable using the process disclosed by Kim. The purity of pharmaceutical compositions is an important consideration when one seeks FDA approval, and for this reason, processes for producing compounds of high purity, and the compounds produced by such processes, are patentably distinct over prior art that only discloses or suggests processes for producing compounds of lower purity.

Accordingly, Kim does not disclose or suggest the subject matter of Claims 16, 17, 21, 22, or 24-26, and these claims are patentably distinct over the Kim reference.

Claim 18 is directed to VA-2914 isopropanol hemisolvate prepared by a process that involves dissolving VA-2914 in isopropanol at a temperature between 75°C and the solvent reflux temperature, allowing the resulting solution to cool down to a temperature

between 0°C and 30°C, and isolating the resulting VA-2914 isopropanol hemisolvate crystalline form. Kim does not disclose isolating VA-2914 isopropanol hemisolvate from a solution of isopropyl alcohol, but rather, formed an isopropyl alcohol solution of VA-2914, and removed the isopropanol solvent by distillation to obtain a residue, which residue was dissolved in ethyl acetate without an intermediate isolation step. Since the product in Kim was eventually obtained by crystallization, albeit from a different solvent, there would have been no motivation to have modified the recrystallization conditions to arrive at the instant isopropanol hemisolvate product.

Claim 19 depends from Claim 18, and includes the additional step of converting the VA-2914 isopropanol hemisolvate to VA-2914 via recrystallization of the VA-2914 isopropanol hemisolvate in a solvent other than isopropanol. Since the Kim reference does not even disclose or suggest isolating the VA-2914 isopropanol hemisolvate, as claimed in Claim 18, Kim further does not disclose or suggest performing the additional process step in Claim 19, namely, recrystallizing the VA-2914 isopropanol hemisolvate from a solvent other than isopropanol.

Claim 20 depends from Claim 19, and specifies that the recrystallization solvent is ethyl ether or a mixture of ethanol and water. Kim does not disclose using these solvents as recrystallization solvents. Claim 23 is directed to isolated VA-2914 isopropanol hemisolvate in crystalline form. As discussed above with respect to Claim 19, Kim does not disclose or suggest producing isolated VA-2914 isopropanol hemisolvate. Rather, Kim merely discloses dissolving VA-2914 in isopropanol, removing the solvent by distillation without crystallizing the product (i.e., a dissolution-evaporation process step), then adding a second solvent to dissolve the material, without a discrete step of isolating the crystalline product.

Accordingly, the subject matter of Claims 18-20 is patentably non-obvious over Kim.

**Request for Continued Examination (RCE)**

Enclosed and submitted herewith is a Request for Continued Examination (RCE) [Form PTO/SB/30]. A Credit Card Form authorizing payment of the applicable RCE fee ($405.00) is enclosed herewith.

**Excess Claims**

The enclosed Credit Card Form also authorizes payment of the applicable excess claims fees, which covers the introduction of five (5) independent claims in excess of three (3) [$550], and four (4) claims over 20 [$104].

Accordingly, payment in the full amount of $1,059.00 (RCE fee + excess claims fees) is authorized on the enclosed Credit Card Form.

The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

## CONCLUSION

In light of the arguments presented above, it is requested that the rejection of the pending claims be withdrawn, and that the patentability of the pending claims likewise be acknowledged. All of Applicants' pending claims are now patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

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**Enclosures:**
**RCE Transmittal [1 pg.]**
**Credit Card Form [1 pg.]**

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